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| EXAMINER | |
|---|---|
| SOROUSH, LAYLA | |
| ART UNIT | PAPER NUMBER |
| 1617 | |
| MAIL DATE | DELIVERY MODE |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/645,951 | WEPFER, SCOTT T. | |
| | Examiner | Art Unit | |
| | LAYLA SOROUSH | 1617 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *27 May 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *19,20 and 24-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19,20 and 24-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

The response filed May 27, 2008 presents remarks and arguments submitted to the office action mailed January 25, 2008 is acknowledged.

Applicant's arguments over the 35 U.S.C. 103 (a) rejection of Claims 19-20, 24, 26, 27 and 30-34 over Mantelle (US Pat. No. 5,446,070) is not persuasive. Therefore, the rejection is herewith maintained.

Applicant's arguments over the 35 U.S.C. 103 (a) rejection of Claims 25, 28, and 29 over Mantelle (US Pat. No. 5,446,070) as applied to claims19-20, 24, 26, 27 and 30-34 above, in view of Swinehart (US Pat. No. 5961997–previously presented) is not persuasive. Therefore, the rejection is herewith maintained.

The ODP rejection made over co-pending Application No. 11/835500 and U.S. Patent No. US 7273887 B1 is withdrawn due to the filing of the Terminal Disclaimers.

Claims 19-20 and 24-34 are pending.

For applicant's convenience the rejections are restated below:

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 19-20, 24, 26, 27 and 30-34 are rejected under 35 U.S.C. 103(a) as being Mantelle (US Pat. No. 5,446,070 –previously presented).

The invention herein reads on a method of reducing pain sensation comprising applying a therapeutically effective amount of an anhydrous gel anesthetic formulation consisting of in an anhydrous mixture at least one anesthetic compound selected from the group consisting of procaine, lidocaine, and tetracaine, a skin penetration enhancer, hydroxypropylcellulose (a gelling agent) with an optional ingredient selected from the group consisting of preservative, fragrance, buffer, and an emollient; and an optional therapeutic agent is selected from the group consisting of: anxiolytic compounds, antiarrhythmics, antibacterials, antibiotics, anticoagulants, anticonvulsants, antifungals, antihistamines, antiinflammatories antivirals, bronchodilators, calcium channel blockers, cytotoxics, and anticancer agents, cytokines, growth factors, immunosuppressives, muscle relaxants, psychotherapeutics, sympathomimetics, vasodilators, and vitamins.

Mantelle teaches a pharmaceutical formulation for topical administration of an anesthetic agent to ameliorate pain. Specifically, in Example 25 the ointment composition consists of lecithin (emollient), propylene glycol (skin penetration enhancer), isocetyl alcohol (emollient), glycerin (preservative), lidocaine base, tetracaine HCL (analgesic), and hydroxypropyl cellulose Klucel, HF (gelling agent),(column 20).

Mantelle teaches a pharmaceutical formulation for topical administration of an anesthetic agent to ameliorate pain. Specifically, in Example 28, the ointment composition consists of lecithin (emollient), propylene glycol (skin penetration

enhancer) in 44 w/w%, glycerin (preservative), Klucel, HF (gelling agent), lidocaine base, and tetracaine HCL (analgesic), (column 21).

The reference teaches the pharmaceutical formulation for topical administration and "topical administration or application means the direct contact of the anesthetic with tissue, such as skin or membrane, particularly the oral or buccal mucosa (col 1 lines 35-55)."

"In particularly preferred embodiments of this invention, the free base local anesthetic agent is selected from the group comprising lidocaine, procaine, propoxycaine, mepivacaine, prilocaine, dyclonine, pramoxine, benzocaine and chloroprocaine. The salt form is preferably one selected from the group comprising prilocaine, tetracaine, bupivacaine, dyclonine, dibucaine, etidocaine and lidocaine salts. The aforementioned bases and salts can be used alone or in combination with other anesthetic bases and salts as needed to achieve therapeutically effective levels when administered transdermally, or through other topical route (col 8 lines 53-65)."

Additionally, Mantelle teaches "the foregoing examples are illustrative embodiments of the invention and are merely exemplary. A person skilled in the art may make variations and modification without departing from the spirit and scope of the invention. All such modifications and variations are intended to be included within the scope of the invention as described in this specification and the appended claims. Ineed, the present invention is intended to encompass and be suitable for use by substituting any of the following drugs for the anesthetic

agent as the pharmacologically active agent in the composition and methods for use of the same (col 23 lines 24-36)."

Mantelle teaches the therapeutic agent can be an anxiolytic compounds (col 35 line 64); antiarrhythmics (col 26 line 30); antibacterials (Col 26 line 51; col 27 line 51) such as Aminoglycosides (Col 26 line 52), Cephalosporins(Col 26 line 66), vancomycin (col 27 line 43), lincosamides (Col 27 line 32), macrolides (col 27 line 33), penicillins (col 27 line 14), antibiotics (col 27 line 51), polypeptides (col 27 line 38), quinolones (col 27 line 57); anticonvulsants (col 28 line 63); antifungals (col 29 lines 61; col 30 line 1); antihistamines (col 30 line 24) such as alkylamine derivatives (col 30 line 25); Phenothiazines (col 30 line 45); Loratadine (col 30 line 50); Cetirizine (col 30 line 43); anti-inflammatories (col 31 line 68); antivirals (col 35 line 49); bronchodilators (col 36 line 16); calcium channel blockers (col 36 line 33) such as arylalkylamines (col 36 line 34); growth factors (col 38 line 55); immunosuppressives (col 39 line 1); muscle relaxants (col 39 line 24), sympathomimetics (col 42 line 20); vasodilators (col 41 lines 3,9, and 22); vitamins (col 41 line 34); Sclerosing agent such as ethanolamine (col 40 line 16); antipruritic such as camphor (col 34 line 10); antiseptic such as thymol Iodide (col 34 line 53); and ectoparasiticide such as crotamiton (col 37 line 64).

Examples 25 and 28 of Mantelle teach a second anesthetic but fail to teach a free base of the second anesthetic. Mantelle teaches optional second therapeutic agent are anxiolytic compounds, antiarrhythmics, antibacterials, antibiotics, anticoagulants, anticonvulsants, antifungals, antihistamines, anti-inflammatories, antivirals, bronchodilators, calcium channel blockers, cytotoxics

and anticancer agents, cytokines, growth factors, immunosuppressives, muscle relaxants, psychotherapeutics, sympathomimetics, vasodilators, and vitamins, as recited in claim 19.

It would have been obvious to one of ordinary skill in the art at the time of the invention to substitute the second anesthetic salt with a free base of the anesthetic or with a second therapeutic agent. The motivation is because Mantelle teaches "the aforementioned bases and salts can be used alone or in combination with other anesthetic bases and salts as needed to achieve therapeutically effective levels" and Mantelle teaches "the foregoing examples are illustrative embodiments of the invention and are merely exemplary. A person skilled in the art may make variations and modification without departing from the spirit and scope of the invention. All such modifications and variations are intended to be included within the scope of the invention as described in this specification and the appended claims. Indeed, the present invention is intended to encompass and be suitable for use by substituting any of the following drugs for the anesthetic agent as the pharmacologically active agent in the composition and methods for use of the same (col 23 lines 24-36)." Hence a skilled artisan would have reasonable expectation of success in achieving the safest clinical outcome by substituting the second anesthetic salt with a free base of the anesthetic or with a second therapeutic agent.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 25, 28, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mantelle (US Pat. No. 5,446,070–previously presented), as applied to claims19-20, 24, 26, 27 and 30-34 above, in view of Swinehart (US Pat. No. 5961997–previously presented).

Mantelle is as discussed above.

Mantelle fails to exemplify the composition claimed wherein lidocaine is present from 0.5-6 total weight percent or an anti-itch agent.

Mantelle teaches the anesthetic agents can comprise about 1 to about 50% by weight of the total composition, hence rendering the claimed limitations obvious (col 5, lines 50-60).

Additionally, Mantelle teaches antipruritics as ingredients in the pharmaceutical compositions (col 34 lines 10-15), hence meeting the limitation of claim 28.

Swinehart teaches a topical composition comprising lidocaine and an anti-pruritic.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to optimize the dose range of Mantelle composition by routine experimentation (see MPEP 2144.05 11) and use an anti-itch agent

because Mantelle teaches (1) the suitable dose range (2) that antipruritics are suitable for such compositions and Swinehart teaches (3) a topical composition comprising lidocaine and an anti-pruritic. The motivation to optimize the dose range of Mantelle's final formulation is because one would have had reasonable expectation of success in achieving the safest clinical outcome.

## *Response to Arguments*

Applicant's arguments filed May 27, 2008 have been considered.

Applicant argues "It is submitted that Mantelle with respect to anesthetic compositions always has an anesthetic base and an anesthetic salt of a different structure(e.g. col. 6, 33-39)." In response, the Examiner respectfully points to the compositions of Mantelle that solely contain e.g. an anesthetic base (see Examples 12-24).

Further, Applicant argues the "consisting of" transitory phase are close ended and Mantelle contain an anesthetic salt and therefore not prior art relevant to the patentability of the pending claims. Examiner respectfully states that the rejection made was based on an obviousness type rejection and not an anticipatory rejection. Therefore, the rejection is proper.

Applicant's argument over claims 25, 28, and 29 rejections depends on the validity of the previous arguments which were not found persuasive.

The arguments are not persuasive and the rejection is made **FINAL**.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**.

See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

## *Conclusion*

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Layla Soroush whose telephone number is (571)272-5008. The examiner can normally be reached on Monday through Friday from 8:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information

for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1617